Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte STANISLAW R. BURZYNSKI

Appeal No. 2003-0899
Application No. 09/603,320

ON BRIEF

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 1-4, 8 and 19-23, which are all of the claims pending in this application.

Claim 1 is illustrative of the claims on appeal and appears in the Appendix to the Appeal Brief, attached.

The prior art reference relied upon by the examiner is:

Hendry et al. (Hendry)	5,238,947	Aug. 24, 1993

References cited by appellant:

Voet et al. (Voet), Biochemistry, Chapter 23, "Lipid Metabolism," John Wiley and Sons, New York, p. 655-656 (undated)

Castillo et al. (Castillo), "Inhibition of Chick Brain Cholesterogenic Enzymes by Phenyl and Phenolic Derivatives of Phenylalanine," Neurochem. Intl, Vol. 18, No. 2, pp. 171-174 (1991)

Grounds of Rejection

Claims 1-4, 8 and 19-23[1] stand rejected under 35 U.S.C. § 103(a) as obvious over appellant's admission in the specification at pages 2-3 in view of Hendry.

We reverse this rejection.

DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellant's specification and claims, to the applied references, and to the respective positions articulated by the appellant and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the noted rejections, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellant's Brief for the appellant's arguments thereagainst. As a consequence of our review, we make the determinations which follow.

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[1] The examiner's Answer, page 3, includes a typographical error which indicates the rejected claims are claims 1-4, 8 and 9-23. This is inconsistent with other statements in the Final Rejection, Answer and the Brief, indicating that the rejected claims are claims 1-4, 8 and 19-23. For purposes of this appeal, the rejected claims are claims 1-4, 8 and 19-23.

35 U.S.C. § 103

Claims 1-4, 8 and 19-23 stand rejected under 35 U.S.C. § 103(a) as obvious over appellant's admission in the specification at pages 2-3 in view of Hendry.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). It is well-established that the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

According to the examiner, "Applicant discloses that compounds such as 3-phenylacetylamino-2,6-piperidinedione and its hydrolysis products are known to block a reaction in the pathway of cholesterol biosynthesis, and as a result these compounds may lower serum cholesterol level[s]." Answer, page 3. The examiner acknowledges that applicant's admissions do not expressly disclose any relationship between the sodium salt of phenylacetylglutamine and 3-phenylacetylamino-2,6-piperdinedione and do not teach the therapeutic amounts employed, nor compositions containing the elected compound, phenylacetylglutamine sodium. Answer, pages 3-4.

Therefore, the examiner relies on Hendry for its disclosure that the initial hydrolysis product of phenylacetylamino-2,6 piperidinedione is phenylacetylglutamine,

which is produced in vivo from phenylacetic acid and glutamine. Answer, page 4. Hendry generally discloses that certain synthetic piperidinedione compounds have cytostatic properties which make them useful for the treatment of cancer. Hendry, column 3.

The examiner concludes (Answer, page 4):

> It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ phenylacetylglutamine (or any salt thereof) in lieu of 3-phenylacetylamino-2,6-piperdinedione as cholesterol lowering agents in methods to inhibit or treat hypercholesterolemia in an affected patient.

In response, appellant argues that the statement in the specification was only meant to convey that it was known in the related art that phenylacetic acid, and analogs thereof could block the formation of isopentylpyrophosphate from 5-pyrophospho-mevalonate, a reaction in the pathway of cholesterol biosynthesis. Brief, page 10. Appellant argues the related art referenced here in the specification was Castillo. Brief, page 11. Castillo, "describes only the use of phenylacetate–and a limited number of related phenyl and phenolic compounds–to cause the in vitro inhibition of mevalonate 5-pyrophosphate (MVAPP) decarboxylase derived from chick brain or liver. *See*, Costillo [sic] *et al.*, page 171, right column." Brief, page 11. According to appellant, the statement in the specification indicated that, "... it was desirable to determine, which, if any, of 3-acetylamino-2,6-piperidinedione and its derivatives can lower serum cholesterol levels...." Specification, page 3, Brief, page 8. Appellant argues there is no teaching in the specification that any of the recited compounds would

be effective to treat or prevent hypercholesterolemia..." Brief, page 5.

Moreover, appellant relies on In re Dow Chemical, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) holding that "a patent applicant's statement of purpose of the work is not prior art." Brief, page 11. Appellant argues that the statement in the specification is a statement of purpose and future course of research and thus, in view of Dow, is not prior art to the claimed invention.

Appellant also argues that "the mere fact that a compound is known to inhibit the in vitro, or even in vivo function of a single enzyme known to be involved in the highly complex and regulated cholesterol biosynthetic pathway, cannot possibly provide proof or a reasonable expectation that using similar compounds would lower serum cholesterol and/or triglyceride levels." Brief, page 6. Appellant concludes, "In view of the manifold factors which regulate serum cholesterol levels, which were well known to those of ordinary skill in the art at the time the application was filed, Appellant asserts that, the combination of art cited by the examiner fails to provide a reasonable expectation of success." Brief, pages 6-7.

We agree with appellant that the examiner has failed to put forth sufficient evidence to support a prima facie case of obviousness. We find appellant's statement in the specification, when read in context, merely reflects a statement of the purpose of the invention, and thus is not considered prior art to the present invention. In re Dow Chemical, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

In the alternative, for the reasons argued by appellant in the Brief, applicant's

admission and the cited reference fail to support a reasonable expectation of success on the part of one of ordinary skill in the art of lowering serum cholesterol levels. In our view the examiner has not provided a sufficient motivation, reason or suggestion for combining the cited references. In particular, Hendry indicates that phenylacetyl-glutamine is an initial hydrolysis product of 3-[N-phenylacetylamino-piperidine]-2,6-dione, which is used as a cancer treatment drug. Even, assuming arguendo, appellant admits that it was known 3-acetylpiperidinedione and its hydrolysis products can block the formation of isopentylpyrophosphate from 5-pyrophosphomevalonate, the examiner has not provided sufficient evidence as to why one of ordinary skill in the art at the time of the invention would have known that either 3-acetylpiperidinedione or other derivatives of acetylpiperidinedione, such as phenylacetylglutamine, would have been useful for lowering serum cholesterol levels. Nor do we find the examiner has indicated in the Answer a sufficient reason, suggestion or motivation to combine Hendry, a reference dealing with an intermediate of a product useful in the treatment of cancer, with appellant's admission of an enzyme present in a reaction pathway of cholesterol biosynthesis, to arrive at a method for the treatment or inhibition of cholesterolemia.

In sum, appellant's alleged admission in the specification of possible use of derivatives of 3-phenylacetylamino-2,6-piperidinedione is not prior art to the present application. Thus, without appellant's admission as prior art, the combination of

references is insufficient to support a prima facie case of obviousness. The rejection of claims 1-4, 8 and 19-23 under 35 U.S.C. § 103(a) for obviousness over appellant's admission in the specification at pages 2-3 in view of Hendry is reversed.

CONCLUSION

The rejection of claims 1-4, 8 and 19-23 under 35 U.S.C. § 103(a) for obviousness over appellant's admission in the specification at pages 2-3 in view of Hendry is reversed.

REVERSED

DEMETRA J. MILLS
Administrative Patent Judge

ERIC GRIMES
Administrative Patent Judge

LORA M. GREEN
Administrative Patent Judge

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) INTERFERENCES

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